

1022783

NOV 19 2002

## **510k Summary**

### **510k Summary for the TL100 Tensymeter Non-invasive Blood Pressure Monitor**

#### **Submitter:**

Tensys Medical, Inc.  
5825 Oberlin Drive Suite 100  
San Diego, CA 92121  
Phone 858-552-1941  
Fax 858-552-1944

#### **Contact:**

Stuart L. Gallant, President

#### **Date prepared:**

#### **Trade Name:**

TL100 Tensymeter Non-invasive Blood Pressure Monitor

#### **Common name:**

Non-invasive blood pressure measurement system.

#### **Classification:**

Class II per 21 CFR 870.1130  
Non-invasive blood pressure measurement system.

#### **Predicate Device:**

Tensys Medical, Inc. believes that the TL100 Tensymeter is substantially equivalent to the Tensys Medical Inc. TL10 Tensymeter(K020537)

### **Device Description:**

The TL100 Tensymeter is a non-invasive blood pressure monitor that utilizes a single patient use non-invasive pressure sensor placed on the wrist, over the radial artery, and an electronic interface module. The device uses proprietary algorithms to analyze the radial artery pressure and display diastolic, systolic, mean blood pressure, pulse rate and a pressure waveform.

### **Intended Use:**

This device is intended for use by medically trained personnel in a clinical setting to continuously monitor and display diastolic, systolic, and mean blood pressures. The device is intended for use on adult patients with a palpable pulse.

### **Comparison of Technological Characteristics of New Device to Predicate Device(s):**

The design of the TL100 Tensymeter utilizes a semiconductor pressure-sensing element applied to the wrist, over the radial artery, to obtain a pressure waveform in the same manner as the predicate device.

### **Clinical Tests:**

Clinical test were performed which show test results which meet or exceed the accuracy requirements of AAMI Standard SP-10 -1992

### **Non-Clinical Tests:**

Patient Contact Materials  
ISO 10993-1

Electrical Safety  
IEC 60601-1

### **Electromagnetic Compatibility**

**IEC 60601-1-2**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

NOV 19 2002

Tensys Medical, Inc,  
c/o Mr. Stuart L. Gallant  
President and Chief Operating Officer  
5825 Oberlin Drive, Suite 100  
San Diego, CA 92121

Re: K022783

Trade Name: TL100 Tensymeter Blood Pressure Monitoring System

Regulation Number: 21 CFR 870.1130

Regulation Name: Non-invasive Blood Pressure Measurement System

Regulatory Class: Class II (two)

Product Code: DXN

Dated: August 21, 2002

Received: August 22, 2002

Dear Mr. Gallant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman for".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Statement of Indications for Use

510(k) Number: \_\_\_\_\_

**Device Name:** TL100 Tensymeter Blood Pressure Monitoring System

### Indications for Use:

This device is intended for use by medically trained personnel in a clinical setting to continually monitor and display diastolic, systolic, and mean blood pressures and pulse rate. The device is intended for use on adult patients with a palpable pulse.

Division of Cardiac, Vascular & Respiratory Devices  
510(k) Number K022783

*DJP 11/14/02*